UNIVERSITY of LOUISIANA LAFAYETTE

HUMAN SUBJECTS RESEARCH TRAINING REQUIREMENT POLICY

Policy #	RE.007.1
Responsible Executive:	Vice President for Research, Innovation, & Economic Development
Responsible Office:	Office of Research Integrity
Originally Issued:	2/21/2024
Latest Revision:	2/21/2024

I. Policy Statement

The University of Louisiana at Lafayette ("University") requires all individuals with the intent to design, conduct, or collaborate with individuals intending to conduct research utilizing Human Subjects to have appropriate training that aligns with current federal regulations governing Human Subjects Research. Investigators and all Research personnel must complete the required training as determined by the University's Office of Research Integrity ("ORI") and the Institutional Review Board ("IRB"). The University requires all IRB members who review Human Subjects Research to complete current IRB member training.

II. Purpose of Policy

The University is obligated to comply with the Protection of Human Subjects Regulations (45 CFR 46) that dictate criteria for the use of Human Subjects in Research and the privacy and confidentiality of their information. This Policy supports the University's compliance with such Protection of Human Subjects Regulations by providing a training requirement to educate all Investigators and Research personnel using Human Subjects in Research to support the growth of generalizable knowledge at the University and all IRB members involved with the review of this Research. The University expects all persons collaborating on Human Subjects Research, including External Collaborators, to have a basic knowledge of the Protection of Human Subjects Regulations and ethics when conducting research with Human Subjects.

A. Investigator and Research Team Member Training

It is the responsibility of Investigators and those involved in Human Subjects Research to maintain current training certification in Human Subjects Research protection. Education in Human Subjects Research protection is required for all faculty, current students, staff, IRB members, and External Collaborators

involved in Human Subjects Research collaborations with the University. This includes but is not limited to the following:

- Principal Investigator(s) on all projects that include research involving Human Subjects;
- Investigators who design the Research protocol;
- Individuals who interact with Human Subjects to conduct study procedures (including obtaining informed consent or assent) or interventions with Human Subjects;
- Individuals who collect data from individuals or enter personally identifiable data for data storage;
- Individuals who use or have access to Private Information that can be linked to Research Human Subjects; and
- Individuals who serve as members of the IRB.

Failure to comply with these requirements will result in a denial of approval to perform the proposed Human Subjects Research until the training requirements are met.

B. Training Requirements

The University requires all individuals who engage in Human Subjects Research to complete one of the following IRB approved Human Subjects protection education training course module bundles **prior to submitting applications seeking IRB approval** for new and continuing research:

1. Basic Human Subjects Research – All University Employees and graduate students engaged in Human Subjects Research must complete this course module. Undergraduate students *may* complete this course but are not required. External Collaborators *may* complete this course if they have not completed other training that meets the IRB's minimum requirement, as stated in Section V.A.3.e below.

2. Undergraduate Training on Human Subjects Research – All undergraduate students engaged in Human Subjects Research must complete this course module. This course module DOES NOT qualify as approved training for Employees or graduate students.

3. Additional Training – Additional required training will be required for IRB members, the IRB Chair, and pursuant to Research endeavors which may require supplemental specified training.

The above training course modules are provided to the University community by the Vice President for Research, Innovation and Economic Development via the Collaborative Institutional Training Initiative ("CITI" or "CITI Program").

ORI and the IRB are charged with reviewing and determining the content of these trainings and any supplemental course modules assigned to Investigators and/or Research personnel to supplement their knowledge of specific topics relevant to their Research.

The IRB shall also evaluate the applicability of trainings from outside entities for External Collaborators.

III. Applicability

This Policy is applicable to and enforceable against all Employees, students, visitors, and individuals affiliated with the University by contract or otherwise (including, but not limited to, non-Employees, such

as vendors and independent contractors, volunteers, student organization advisors, External Collaborators, and retirees).

IV. Definitions

1. **Employee**: is any classified or unclassified faculty or staff member of the University.

2. **External Collaborator**: is an individual who is conducting Research with a member of the University community and is not employed by nor a student at the University.

3. **Human Subjects**: is defined in 45 C.F.R. 46.102(e)(1) as a living individual about whom an Investigator (whether professional or student) conducting Research:

    i. Obtains information or biospecimens through Intervention or Interaction with the individual and uses, studies, or analyzes the information or biospecimens; or

    ii. Obtains, uses, studies, analyzes, or generates Identifiable Private Information or Identifiable Biospecimens.

4. **Intervention**: is defined in 45 C.F.R. 46.102(e)(2) as including both physical procedures by which information or biospecimens are gathered (e.g., venipuncture) and manipulations of the subject or the subject's environment that are performed for Research purposes.

5. **Interaction**: includes communication or interpersonal contact between the Investigator and the Human Subject.

6. **Private Information**: includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information that has been provided for specific purposes by an individual and that the individual can reasonably expect will not be made public (e.g., a medical record, educational records, etc.).

7. **Identifiable Private Information**: is Private Information for which the identity of the Human Subject is or may readily be ascertained by the investigator or associated with the information.

8. **Identifiable Biospecimen:** is a biospecimen for which the identity of the Human Subject is or may readily be ascertained by the Investigator or associated with the biospecimen.

9. **Institutional Review Board** ("IRB"): is a committee charged with protecting the rights and welfare of Human Subjects in Research. The primary function is to review and approve all Research involving Human Subjects to ensure safety, privacy, and confidentiality for the participants and their data. The constitution of the IRB is stipulated in 45 C.F.R. 46.107. Its function and operation are stipulated in 45 C.F.R. 46.108.

9. **Investigator**: is any individual who is involved in conducting Human Subjects Research studies for this Policy and Health and Human Services Regulations. Such involvement would include:

    i. Obtaining information about Human Subjects by Intervening or Interacting with them for Research purposes;

    ii. obtaining Identifiable Private Information about Human Subjects for Research purposes;

iii. Obtaining the voluntary informed consent of individuals to be Human Subjects in Research; and

iv. Studying, interpreting, or analyzing Identifiable Private Information or data for Research purposes.

Investigators can include physicians, scientists, nurses, administrative staff, teachers, and students, among others.

10. **Principal Investigator**: is the person designated with overall responsibilities for a Research study.

11. **Research**: is defined in 45 CFR 46.102(l) as a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge. Activities that meet this definition constitute Research for purposes of this Policy, whether or not they are conducted or supported under a program that is considered Research for other purposes (e.g., some demonstration and service programs may include Research activities; collecting data from or about students and student performance with the intent to create generalizable knowledge and publish or distribute the information outside of the University is Research). For purposes of this Policy, the following activities are deemed NOT to be Research:

    i. Scholarly and journalistic activities (e.g., oral history, journalism, biography, literary criticism, legal research, and historical scholarship), including the collection and use of information, that focus directly on the specific individuals about whom the information is collected.

    ii. Public health surveillance activities, including the collection and testing of information or biospecimens, conducted, supported, requested, ordered, required, or authorized by a public health authority. Such activities are limited to those necessary to allow a public health authority to identify, monitor, assess, or investigate potential public health signals, onsets of disease outbreaks, or conditions of public health importance (including trends, signals, risk factors, patterns in diseases, or increases in injuries from using consumer products). Such activities include those associated with providing timely situational awareness and priority setting during the course of an event or crisis that threatens public health (including natural or man-made disasters).

    iii. Collection and analysis of information, biospecimens, or records by or for a criminal justice agency for activities authorized by law or court order solely for criminal justice or criminal investigative purposes.

    iv. Authorized operational activities (as determined by each agency) in support of intelligence, homeland security, defense, or other national security missions.

V. Policy Procedure

A. CITI Training Instructions and Required Course Modules

The University subscribes to the CITI Program for online Human Subjects Research training. Prior to submission of a Human Subjects Research application to the IRB, Investigators shall complete all training minimum requirements as indicated in Section V.A.3. below. Additionally, when a revision to an IRB

application is requested to add additional Research personnel, those individuals must also complete training as specified below.

1. Investigators and Research personnel are required to either:

   a. Utilize this "Log In Through My Organization" link (www.citiprogram.org/?pageID=668) to login with University credentials, or

   b. Register at CITI (http://about.citiprogram.org) and affiliate with the University of Louisiana at Lafayette.

2. Upon the initial completion of the training, Investigators and Research personnel must then complete the profile information as appropriate.

3. When "Selecting Curriculum", Investigators shall follow the minimum requirements below:

   a. **Undergraduate Students**: Undergraduate students shall select "Undergraduate Training on Human Subjects Research" which includes the following required CITI course modules:

      - History and Ethical Principles – SBE (ID 490);
      - Informed Consent – SBE (ID 504);
      - Privacy and Confidentiality – SBE (ID 505);
      - Internet-Based Research – SBE (ID 510); and
      - Populations in Research Requiring Additional Considerations and/or Protections (ID 16680).

   b. **Graduate Students, Employees, and IRB Members**: Graduate students, Employees, and IRB members shall select "Basic Human Subjects Research" which includes the following required CITI course modules:

      - Belmont Report and Its Principles (ID 1127);
      - History and Ethical Principles - SBE (ID 490);
      - Defining Research with Human Subjects - SBE (ID 491);
      - The Federal Regulations - SBE (ID 502);
      - Assessing Risk - SBE (ID 503);
      - Informed Consent - SBE (ID 504);
      - Privacy and Confidentiality - SBE (ID 505);
      - Populations in Research Requiring Additional Considerations and/or Protections (ID 16680);
      - Internet-Based Research - SBE (ID 510);

- Social and Behavioral Research (SBR) for Biomedical Researchers (ID 4); and
- Conflicts of Interest in Human Subjects Research (ID 17464).

c. **IRB Members**: In addition to Section V.A.3.b above, IRB members shall also be required to take the following CITI course modules (requirement of said course modules may be amended by vote of the IRB in a full board meeting):

- The IRB Member Module - 'What Every New IRB Member Needs to Know' (ID 816);
- The IRB Administrator's Responsibilities (ID 13813);
- Single Institutional Review Board (sIRB) Use and Administration: When Relying on a sIRB (ID 17387); and
- Data and Safety Monitoring in Human Subjects Research (ID 17433).

d. **IRB Chair**: In addition to Section V.A.3.b above, the IRB Chair shall also be required to take the following CITI course modules:

- Role and Responsibilities of an IRB Chair (ID 15386);
- IRB Chair Meeting Responsibilities (ID 15387); and
- The IRB Chair's Role Outside of the IRB Meeting (ID 15388).

e. **External Collaborators**: External Collaborators must minimally show completion of the following CITI course modules or the equivalent:

- Defining Research with Human Subject – SBE (ID 491);
- The Federal Regulations – SBE (ID 502);
- Assessing Risk – SBE (ID 503);
- Informed Consent – SBE (ID 504); and
- Privacy and Confidentiality – SBE (ID 505).

Adding External Collaborators to the University's CITI Program is free of cost. External Collaborators may add an affiliation with the University to their existing CITI registration by using the "Add Affiliation" link on the home page after logging in to CITI.

4. Certificates of Completion are stored within the CITI Program and are always accessible with an account. The Principal Investigator is responsible for keeping Certificates of Completion from External Collaborators on file and providing them to the IRB upon request.

B. Training Recertification

Recertification of the curriculum referenced in Section V.A.3 above must take place every five (5) years from the date of initial certification through CITI.

C. IRB Member Special Requirements

New IRB members will be probationary, non-voting members during their first semester while they complete the required training and observe how the IRB committee functions. IRB Members unable to complete the training within the first semester will be granted one additional semester of probationary status to allow them time to complete the training. Upon completion of the required training, probation is lifted, and IRB members may vote and review applications.

Continuing IRB members should complete re-training prior to the expiration date of the training (i.e., every five (5) years). Members unable to complete retraining prior to the expiration date will be granted a one semester extension. Upon completion of the required training, members may again vote and review applications.

D. Additional Training Requirements

1. FERPA Training. The IRB may require Family Educational Rights and Privacy Act ("FERPA") training (i.e., FERPA: An Introduction [ID 17407], FERPA for Researchers [ID 17410], or an equivalent) when an Investigator and/or Research personnel requires access to educational records.

2. HIPAA Training. The IRB may require Health Insurance Portability and Accountability Act ("HIPAA") training (i.e., Research and HIPAA Privacy Protections [ID 14], or an equivalent) when medical records are needed for Research purposes.

3. Additional Other Training. The IRB Chair may require or suggest additional training course modules as appropriate for the Research topic and experience of the Investigator.

VI. Enforcement

The IRB, ORI, and the Vice President for Research, Innovation, and Economic Development are responsible for the enforcement of this Policy. Failure to comply with training requirements will result in the IRB withholding approval or suspending the activity of the Research project that involves Research personnel who fail to meet the requirements of this Policy.

When IRB members fail to complete their required training within the expected timeframe, they will be notified that it must be completed by the end of the following semester. Members not completing the required training by the end of the extension period will have their names submitted to the Vice President for Research, Innovation and Economic Development with a request for replacement.

VII. Policy Management

Upon adoption, the Vice President for Research, Innovation, and Economic Development shall be the Responsible Executive for this Policy and in charge of the management of this Policy. The Director of ORI is the Responsible Officer for this Policy. ORI is the Responsible Office for this Policy.

VIII. Exclusions

Individuals who are not involved in Human Subjects Research are excluded from this Policy. The IRB may waive additional training when evidence of equivalent training is presented in lieu of CITI training certifications. Investigators receiving fully de-identified and non-identifiable data sets, as determined by the IRB, are excluded from this Policy.

IX. Effective Date

This Policy is effective on the date of the University President's approval signature.

X. Adoption

This Policy is hereby adopted on this 2/21/2024.

DocuSigned by:
Joseph Savoie
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Dr. E. Joseph Savoie
President

XI. Appendices, References and Related Materials

- CITI Program Registration Instructions for Human Subject Training
- Collaborative Institutional Training Initiative (CITI Program)
- Health Insurance Portability and Accountability act of 1996
- U.S. Department of Health and Human Services
- Protection of Human Subjects Regulations 45 C.F.R. 46
- FERPA Laws 34 C.F.R. 99.1(a)
- Policy for the Protection of Human Subjects in Research

XII. Revision History

- Adoption of Human Subjects Research Training Policy: 2/21/2024 (RE.007.1).